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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,046	02/08/2001	Kangsheng Wang	258/193	9275
34055	7590	03/09/2004	EXAMINER	
PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			TON, THAIAN N	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/781,046

Applicant(s)

WANG, KANGSHENG

Examiner

Thai-An N Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/8/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The Request for Continued Examination under 37 CFR § 1.114 is proper and has been entered. Applicants' Response, filed 2/9/04, has been entered. Claims 22-26 have been amended.

Claims 1-26 are pending. Claims 22-26 are under current examination.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of claims 22-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' submit a 37 C.F.R. 1.132 Affidavit [the Wang Declaration] to show that more than one antibody has been made according to the methods taught by the specification. Particularly, that 1B3 (1A8), 2D4 (1F3), 3C7 (2C5), 2E8 (2G5), 4E7 (1F11), and 1F5 (1D8) have been made according to the method disclosed in the specification. These antibodies have binding affinity to sperm cells and retain the ability of the sperm to fertilize oocytes. Additionally Applicants state that more

than one antibody (mAbC and mAbD) have demonstrated that sperm cells bound with the antibody are able to carry the transgene DNA and fertilize an oocyte from which a transgenic animal develops and contains the transgene. See pp. 3-4 of Applicants' Response.

The declaration states that Appendix A shows that a number of hybridoma supernatants were generated from mice immunized by mouse sperm cells which do not prohibit sperm from fertilizing oocytes. Particularly, that the hybridoma supernatants were incubated with sperm cells and then incubated with oocytes for testing of *in vitro* fertilization. The declaration states that some of the supernatants [1B3, 1F5, 2D4, 3E8, 3C7 and 4E7] did not inhibit fertilization. Then, in a re-testing process particular sub-supernatants [1A8 from 1B3, 1F3 from 2D4, 2C5 from 3C7, 2G5 from 2E8, 1F11 from 4E7, and 1D8 from 1F5] allowed the sperm to retain the ability to fertilize. See pp. 2-3 of the declaration. These sub-supernatants [renamed A, B, C, D, E, and F] were then used in flow cytometry analysis to see if the antibodies bound to sperm cells. It was found that mouse antibodies A, B, C and D bound to mouse sperm cells and that mAbC and mAbD have both been shown to carry transgene DNA into an oocyte, from which a transgenic mouse develops. The mice were analyzed by Southern blot in order to confirm if the transgene was inserted into their genome. See p. 3 of the Declaration.

The Wang Declaration has been considered but is not found to be persuasive. Particularly, the declaration states the sub-supernatants were re-tested. This is

unclear if the sub-supernatants are produced from same original hybridoma clone, or different clones, and further the declaration fails to state if the various sub-supernatants recognize different epitopes on the surface of the sperm. The declaration fails to address if the various sub-supernatants A, B, C, D, E and F recognize the same epitope or different epitopes? If they all recognize the same epitope, then they would be the same antibody [mAbC] and not different antibodies, as stated in the declaration.

Applicants draw a parallel between *In re Wands* and the instant invention because in Wands, the claimed invention was directed to a method for immunoassay of HbsAg using high-affinity monoclonal IgM antibodies. Prior to Wands, most immunoassays used IgG isotype and the IgM were disfavored because of their sensitivity to reducing agents and their tendency to self-aggregate and precipitate. The position of the PTO was that the producing of high-affinity IgM anti-HbsAg antibodies was unpredictable and unreliable, and thus, undue experimentation would be required to make the antibodies. The Court ruled that undue experimentation would not be required to practice the claimed invention when disclosure provides considerable direction and guidance on how to practice the invention and presents working examples, and that all the methods were known in the art. Accordingly, Applicants conclude that because the present application is a continuation-in-part of Application No. 09/537,861, which provides considerable

guidance and direction with regard to making and screening sperm-specific antibodies. See p. 4 of Applicants' Response.

This is not found to be persuasive. The specification does not disclose a repeatable process to obtain the antibody linker and it is not apparent if it is readily available to the public. Accordingly, it is maintained that mAbC is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the antibody mAbC is not so obtainable or available, the requirements of 35 U.S.C. 112, regarding "how to make" may be satisfied by a deposit of mAbC. Furthermore, the Wang Declaration fails to overcome the prior rejection for reasons of record and those recited in the preceding paragraphs.

Once the deposit has been perfected, the claims will be limited the antibody, mAbC, which is characterized by having binding affinity to sperm cells from a plurality of species of animals, wherein a sperm cell bound with the antibody mAbC retains the ability to fertilize an oocyte.

It is maintained that it is well-known that the state of the art of antibodies directed to sperm is such that one of skill in the art would expect such antibodies to inhibit fertilization for reasons of record advanced in prior Office actions. MPEP §2164.05(a) states that:

*Whether the specification would have been enabling as of the filing date involves consideration of the nature of the invention,*

*the state of the prior art, and the level of skill in the art. The initial inquiry is into the nature of the invention, i.e., the subject matter to which the claimed invention pertains. The nature of the invention becomes the backdrop to determine the state of the art and the level of skill possessed by one skilled in the art. The state of the prior art is what one skilled in the art would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains. The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed.*

The state of the art at the time the claimed invention was replete with art showing that antibodies directed to sperm was such that one would expect the inhibition of fertilization. [See Yan, Nakamura, Naz and Kim, all cited in prior Office actions]. As such, when taken with the state of the art and lack of teaching in the specification for the generation of sperm-specific antibodies which, when bound to a sperm, would allow a sperm to retain the ability to fertilize an oocyte, other than the exemplified mAbC, it is maintained that the claimed invention is enabled only for the antibody mAbC.

Accordingly, when taken with state of the art of sperm-specific antibodies, with particular regard to the inhibition of fertilization, and the quantity of experimentation necessary for the production and use of the antibody characterized by having binding affinity to a sperm cell, wherein the sperm cell bound with the antibody retains the ability to fertilize an oocyte, would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

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*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

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